



GRAIL and England's National Health Service (NHS) Present Trial Design for Largest Study of Multi-Cancer Early Detection Test at ASCO Annual Meeting

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NHS-Galleri Trial Evaluates Clinical Utility of GRAIL's Galleri® Multi-Cancer Early Detection Test Alongside Current Standard of Care to Reduce Later-Stage Cancer Diagnoses

Study Prioritizes Equitable Recruitment Approaches to Help Ensure Enrollment is Representative of Overall Population of People with Cancer

Collaboration Aims to Help UK Meet Goal of Diagnosing Three-Quarters of All Cancers at an Early Stage by 2028

MENLO PARK, Calif., June 6, 2022 —GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, announced today that the study design of the NHS-Galleri trial was presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. The poster, titled "NHS-Galleri Trial Design: Equitable Study Recruitment Tactics for Targeted Population-Level Screening With a Multi-Cancer Early Detection (MCED) Test," was presented by Professor Charles Swanton, MD, PhD, a cancer researcher and oncologist at University College London and the Francis Crick Institute, chief clinician, Cancer Research UK, and co-chief investigator of the study (Abstract #TPS6606).

The NHS-Galleri trial is a randomized and controlled clinical trial in the NHS' clinical practice setting. It is the largest study of an MCED test, enrolling 140,000 healthy volunteers aged 50-77 in select regions throughout England who have not had a cancer diagnosis or undergone treatment for cancer in the last three years. Regions in the UK were selected to include areas of high cancer mortality, socioeconomic deprivation and ethnic diversity, using innovative methods to enroll a study population with a reasonable number of participants from all socioeconomic groups and major ethnic minority groups.

The study's aim is to determine if the Galleri test, along with other standard cancer screenings, can find cancers at an early stage when they are less advanced, and patients have a higher chance of successful and potentially curative treatment. It will assess absolute numbers of stage 3 and 4 cancers diagnosed at 3.5 years following randomization.

"This study has the potential to be game changing for early cancer detection, as we evaluate an unprecedented number of healthy volunteers and work to ensure participants are representative of the entire population with cancer," said Dr. Swanton. "Unfortunately, many cancers are found too late, when they are more advanced and difficult to treat. We know early diagnosis saves lives, and we think this test could be a key to increasing cancer survival rates for more people."

The collaboration between GRAIL and the NHS supports the NHS Long Term Plan to transform cancer care with three in four cancers diagnosed at an early stage by 2028. More than 100,000 participants have been enrolled to date. Enrollment is expected to be completed in July 2022, and initial trial results are expected in 2024. If successful, the NHS plans to extend the rollout to an additional 1 million people in 2024 and 2025.

"We share a commitment with the NHS to have data that is representative of society at-large and all people with cancer and ensuring that access to cancer screening and earlier diagnosis is accessible and equitable," said Josh Ofman, MD, MSHS, president, GRAIL. "The current approach for screening and diagnosing cancer is not as effective as it could be and we are committed to changing the status quo. We are proud to be working with the NHS on this groundbreaking, large-scale, population screening program that has the potential to fundamentally transform early cancer detection."

In a [clinical study](#), the Galleri test demonstrated the ability to detect signals across more than 50 types of cancer, as defined by the American Joint Committee on Cancer Staging Manual, over 47 of which lack recommended screening tests today in the UK. GRAIL's Galleri test has a false positive rate under 1% and it can predict where cancer originated with 89% accuracy.

"We applaud the UK Government and the NHS for their leadership in setting the roadmap to achieve their goal of diagnosing three-quarter of all cancers at an early stage by 2028," said Sir Harpal Kumar, president of GRAIL Europe. "A reduction in late-stage cancer is thought to precede a reduction in deaths and is also associated with other beneficial patient outcomes, including the ability to receive effective therapy and improve quality of life."

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About NHS-Galleri trial

For the prospective, partially blinded, randomized trial, all study participants will provide a blood sample during three annual visits to a mobile health clinic—at baseline, year 1 and year 2. After the first visit, participants are randomized 1:1 into either the intervention or control arm. Participants in the intervention arm will have their blood tested by the Galleri test. Blood samples from subjects in the control arm will not be tested immediately, but will be stored for potential future testing. If a cancer signal is detected for those in the intervention arm, research staff will explain the result and schedule an appointment for follow-up tests at an NHS hospital local to the participant. All participants in the study will be followed for cancer and other related outcomes via NHS databases and will be reminded to continue to have guideline-recommended cancer screenings.

The study is sponsored by GRAIL and is being run by Cancer Research UK and King's College London Cancer Prevention Trials Unit (UK), in collaboration with eight cancer alliances in England.

About GRAIL

GRAIL is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on alleviating the global burden of cancer by developing pioneering technology to detect and identify multiple deadly cancer types early. The company is using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to enhance the scientific understanding of cancer biology, and to develop its multi-cancer early detection blood test. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom. GRAIL, LLC, is a subsidiary of Illumina, Inc. (NASDAQ:ILMN) currently held separate

from Illumina Inc. under the terms of the Interim Measures Order of the European Commission dated 29 October 2021.

For more information, please visit grail.com.

About Galleri®

The earlier that cancer is detected, the higher the chance of successful outcomes. The Galleri

multi-cancer early detection test can detect signals across more than 50 types of cancer, as defined by the American Joint Committee on Cancer Staging Manual, through a routine blood draw. When a cancer signal is detected, the Galleri test predicts the cancer signal origin, or where the cancer is located in the body, with high accuracy to help guide the next steps to diagnosis. The Galleri test requires a prescription from a licensed healthcare provider and should be used in addition to recommended cancer screenings such as mammography, colonoscopy, prostate-specific antigen (PSA) test, or cervical cancer screening. It is intended for use in people with an elevated risk of cancer, such as those aged 50 or older.

For more information about Galleri, visit galleri.com.

Important Galleri Safety Information

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Results should be interpreted by a healthcare provider in the context of medical history, clinical signs and symptoms. A test result of "Cancer Signal Not Detected" does not rule out cancer. A test result of "Cancer Signal Detected" requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer.

If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body. False-positive (a cancer signal detected when cancer is not present) and false-negative (a cancer signal not detected when cancer is present) test results do occur. Rx only.

Laboratory/Test Information

GRAIL's clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. The Galleri test was developed, and its performance characteristics were determined by GRAIL. The Galleri test has not been cleared or approved by the U.S. Food and Drug Administration. GRAIL's clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

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